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No. 93-2052

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1994

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR CERTIORARI

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SUMMARY OF ARGUMENT

In determining whether sufficient reasons exist for granting certiorari, this Court focuses on whether the presented issues are of importance to the public as distinguished from the individual concerns of the litigants. *E.g., N.L.R.B. v. Pittsburgh S.S. Co.*, 340 U.S. 498, 502 (1951).

The issue of whether the Nuremberg Code's ethical standards are encompassed within due process or federal common law is a special and important issue squarely before this Court. Moreover, as hereinafter set forth, the Nuremberg Code issues were sufficiently preserved in the lower courts.

Further, a controversy does exist among the Circuit Courts of Appeal as to when mandamus will issue to review and correct procedurally defective class action certification proceedings.

The ruling on class action certification is often the most significant decision rendered by the district court in class action proceedings.[1] *Deposit Guaranty Nat'l Bank v. Roper*, 445 U.S.

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[1]Proceedings in this case confirm the truism announced by *Roper*. After the original *Petition for Writ of Mandamus* was filed, the trial court announced a nationwide $4.3 billion settlement. *See* Appendix, A-162. The problem is that the settlement only covers women who have suffered a "personal injury." (*See* Appendix A-162 at ¶ 2(a)(1).) On the other hand, the Nuremberg Code would cover those women who are not yet injured. Specifically, the Nuremberg Code would require full disclosure of all foreseeable risks to every woman who has had a breast implant; and the Code would permit any women to withdraw from the experiment (i.e., to have explant surgery). Nothing in the current settlement requires a full disclosure of

326, 339 (1980). However, in this case, the district court provided no notice, and declined to grant a hearing on petitioners' motion to certify the class. The Court also did not make specific factual findings as required by F.R.C.P. 52(a) and as suggested by F.R.C.P. 23. The Eleventh Circuit Court of Appeals effectively rubber-stamped the district court's misconduct. Thus, this case presents the issue of whether mandamus should issue to correct the deficient class certification proceedings. It is a special and important reason for granting certiorari because the issue invokes the supervisory powers and duties of this Court.

Finally, the petition presents this Court with a unique and valuable opportunity to refine its decision in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1931). Since the *Erie* decision, no clear test has been expressed for determining whether federal common law should or will be applied to nationwide tort litigation.

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risks. *See* Appendix A-162. In short, a major purpose of the Nuremberg Code is to prevent future injury. On the other hand, the scope of the current settlement is to pay for past or future injuries.

If this *Petition for Certiorari* is not granted, no one will ever know if the settlement should have been $4 billion or $14 billion. Furthermore, countless women will not be given an opportunity to avoid injury *before* it occurs.

ARGUMENT

POINT I

WHETHER THE NUREMBERG CODE'S ETHICAL STANDARDS ARE ENCOMPASSED WITHIN DUE PROCESS OR FEDERAL COMMON LAW IS A SPECIAL AND IMPORTANT ISSUE JUSTIFYING CERTIORARI

A. The Nuremberg Code.

The Nuremberg Code's ethical standards are not, as Dow Corning characterizes them "no legal authority." In *United States v. Stanley*, 483 U.S. 669, 687 (1987), Justice Brennan, in a concerning and dissenting opinion, noted that the Code, although a product of a military tribunal, applies to both soldiers and civilians, and that "experimentation with unknowing human subjects is morally and legally unacceptable." 483 U.S. at 687. Similarly, Justice O'Connor concluded that if the voluntary consent required by the Code is violated, due process guarantees compensation. 483 U.S. at 710.

Further, the Nuremberg Code claim is a distinct legal theory and provides a unique remedy for unlawful experimentation -- termination of the experiment. A copy of the Code is in the Appendix to this reply brief. A-162, *infra*.

B. Proceedings in the Lower Courts.

When the trial court denied the petitioners' motion to certify the class, the court also rejected the Nuremberg Code as a viable legal theory. The court began by invoking laughter at the Code claim:

> THE COURT: Before you say anything, I am going to deny the motion for class certification.
>
> (Laughter.)

(Pet. App. at p. A-13.)

Next, the court expressed doubt that a Nuremberg Code claim is an appropriate claim.

> To the extent that these are appropriate claims . . . that is in no way a ruling on the merits of whether any such claims could be presented individually or as a class theory.

(*Id.* at pp. A-13, 14.)

Finally, the Court failed to acknowledge the unique nature and remedies contained in the Nuremberg Code when it ruled:

> [T]o the extent we're going to have a class, I can deal with it in other litigation without the need to utilize this particular device for certain limited theories of action.

(*Id.* at A-14.)

However, the district court cannot deal adequately with the Nuremberg Code claim absent a class action certification. Only the petitioners pled a Code claim. Unless the complaint is certified as a class action, women will not have the benefit of the Code's ethical standards, ease of proof and unique remedy.[2] Therefore, unless the Code's universal standard of care is applied to a universal class the court cannot adequately deal with the Code.

More importantly, the laughter, the court's failure to acknowledge the Code claim, and its failure to appreciate the Code's

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[2]See footnote 1, above.

standards, ease of proof and remedy all show that the Court rejected the Code as a legal theory.[3] Further, since the rejection of the Code was tacitly approved by the Eleventh Circuit Court of Appeals when it denied the subsequent petition for mandamus, the issue of whether the Code is part of due process or federal common law is ripe for decision.

C. Why the Nuremberg Code Issue is Special and Important.

In *Erie R. Co.*, *supra*, certiorari was granted "because of the importance of the question of whether the federal court was free to disregard the alleged rule of the Pennsylvania common law. . . ." *Erie R. Co.*, *supra* at 71. Similarly, in this case, the petition presents three possibilities: (1) the Court could rule that the Code's principles are within due process; (2) the Court could rule that the Code's principles are part of the common law; or (3) the Court could conclude that a nationwide tort class action case requires a federal common law ethical standard.[4] *C.f.*, *Moragne v. States Marine Lines*, 398 U.S. 375 (1970) (holding that an

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[3] Even if the Nuremberg Code claim was not completely adjudicated in the trial court, certiorari is justified. When there were problems in the class action hearings requiring resolution, the Court may grant certiorari to resolve the class action issues prior to trial. *See Eisen v. Carlisle and Jacquelin*, 417 U.S. 156, 159 (1974) (certiorari granted to resolve questions involving petitioner's attempt to maintain his suit as a class action).

[4] The need for uniformity is the most frequently cited reason for fashioning federal common law. Annot: *The Supreme Court and the Post Erie Federal Common Law*, 31 L. Ed.2d 1006, 1014 (1972).

action lies under federal, general maritime law for death caused by a violation of maritime duties in state waters). The three possibilities illustrate just how important the special issue is. This Court has a unique opportunity to revisit and refine *Erie R. Co.*

POINT II

THIS CASE PRESENTS A CONTROVERSY AMONG THE CIRCUIT COURTS OF APPEAL OVER WHEN MANDAMUS MAY ISSUE TO REVIEW AND CORRECT DEFECTIVE CLASS CERTIFICATION PROCEEDINGS

The issue of when a Circuit Court of Appeals may issue mandamus to review and correct defective class certification proceedings is a controversial issue. The Third Circuit Court of Appeals, in *Lusardi v. Lechner*, 855 F.2d 1062 (3d Cir. 1981), ruled that mandamus is unnecessary and unavailable unless there is a clear error of law and there is no adequate, alternate remedy. The Eighth Circuit issues mandamus if the district court acts outside its jurisdiction or disregards a statute. *Schmitt v. Fuller Brush Co.*, 527 F.2d 532 (8th Cir. 1975). The Eleventh Circuit Court of Appeals, theoretically, will issue mandamus if the district court ignores notice and hearing procedural safeguards. *In re Temple*, 851 F.2d 1269 (11th Cir. 1988). However in this case, the Eleventh Circuit declined to issue mandamus. The Ninth Circuit Court of Appeals issues mandamus if the district court arbitrarily applies Rule 23 of the Federal Rules of Civil Procedure. *McDonnell-Douglas Corp. v. The United States District Court for the Central District of California*, 523 F.2d 1073 (9th Cir. 1975).

The Tenth Circuit uses mandamus to protect against excessive zeal in the grant or denial of class certification. *West v. Capitol Federal Savings & Loan Ass'n*, 558 F.2d 977, 982 (10th Cir. 1977).

The controversy among the Circuit Courts over when mandamus will issue to review a defective class certification proceeding qualifies as a special and important reason for granting certiorari.

POINT III

THE DISTRICT COURT'S DEPARTURE FROM THE USUAL COURSE OF PROCEEDINGS QUALIFIES THIS CASE FOR CERTIORARI

A. The District Court's Departure from the Usual Course of Proceedings.

The District Court's failure to hold a hearing and resolve the factual issues inherent in the motion to certify the class action was a usurpation of judicial power; hence, mandamus is warranted. (Petition for Certiorari pp. 22-23.) So was the Court's failure to make meaningful findings on each factual element contained in F.R.C.P. 23. *See Commissioner v. Duberstein*, 363 U.S. 278, 292 (1960) ("[t]here comes a point where findings become so sparse and conclusory . . . [that] such . . . findings do not constitute compliance with Rule 52's direction. . . .").

B. Petitioners Allege a Clear and Indisputable Right to Issuance of the Writ of Mandamus.

A district court's ruling on the certification issue is often the most significant decision in a class action lawsuit. *Deposit Guar-*

anty Nat'l Bank v. Roper, 445 U.S. 326, 339 (1980). Frequently, as in this case, the decision determines whether claimants with moderate claims will have access to judicial relief that otherwise would be economically unavailable by means of individual litigation. *Id.* at 339. Thus, unless it is apparent from the pleadings that the Rule 23 requirements are or are not met, the court should hold a meaningful hearing. *See also General Telephone Co. of the Southwest v. Falcon*, 457 U.S. 147, 160 (1982).

The petitioners' right to notice, a meaningful hearing, and meaningful findings springs from three sources: (1) due process; (2) F.R.C.P. 23, construed by the Courts as requiring a hearing when the factual issues of numerousity, commonality, typicality and manageability are disputed; and (3) the district court's duty to manage class action litigation. (Petition for Certiorari, pp. 20-21.) The petitioners' right to meaningful findings is mandated by F.R.C.P. 52.

In summary, petitioners alleged a clear and undisputable right to notice, a hearing, and meaningful findings. What is unresolved is the issue of whether petitioners are entitled to review of the class certification proceeding via the writ of mandamus. That this issue is a controversial, unresolved issue -- instead of a clear, undisputable issue -- does not militate against certiorari. Rather, it is a special and important reason for granting certiorari. (*See* Point II of this brief.)

POINT IV

THE PETITIONERS ARE NOT ASKING THIS COURT TO INVOLVE ITSELF IN AN AREA WITHIN THE DISTRICT COURT'S DISCRETION

Dow Corning says, "The petitioners have shown no reason why this Court should involve itself in multi-district litigation in an area within the Court's discretion." (Brief of Respondent p. 12.) But, Dow Corning fails to identify the "area of discretion." The court did not have discretion to decline notice and a hearing. *See Sirota v. Solotron Devices, Inc.*, 673 F.2d 566, 571 (2nd Cir. 1982) ("there can be no dispute that it is proper for a district court . . . to conduct hearings to determine whether the prerequisites of Rule 23 are satisfied.") Implicitly, Dow Corning concedes that a hearing was required when it says that the MDL 926 status conference "was a hearing in keeping with normal practice . . . ." (Brief of Respondent, p. 13). However, the so-called hearing was no more than a denial from the bench of the petitioners' motion to certify the class. *The petitioners were not even notified that the Court would rule on their motion to certify the class at the status conference*. For that reason, petitioners' counsel did not attend. The bench announcement was not the kind of hearing required to resolve the factual issues inherent in Rule 23, and mandated by due process.

Dow Corning also does not explain how granting certiorari would interfere with the MDL proceeding. If certiorari is granted and mandamus ordered, the lower district court will simply be

required to provide notice, a meaningful hearing and meaningful findings. That is not interference. It is due process.

CONCLUSION

The issues raised in the Petition for Certiorari are special and important issues warranting certiorari. Together, the issues involve complex, unresolved questions of Constitutional and federal common law. Moreover, the Circuit Courts of Appeals are not in agreement over when a defective class action proceedings can be reviewed and corrected via mandamus. Granting certiorari does not interfere with the lower court's discretion. Rather, the lower court's departure from the usual course of proceedings is another special and important reason warranting certiorari.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	
SILICONE GEL BREAST	)	Master File No.
IMPLANT PRODUCTS	)	CV 92-P-10000-S
LIABILITY LITIGATION	)	
(MDL 926)	)	
HEIDI LINDSEY, et al.,	)	
Plaintiffs,	)	
	)	
-vs.-	)	Civil Action No.
	)	CV 94-P-11558-S
DOW CORNING CORP., et al.)		
Defendants.	)	

FINAL ORDER AND JUDGMENT (Corrected)

In accordance with the findings and conclusions contained in the Opinion filed herewith, the Settlement Agreement[1]--with the modifications made in prior orders, in the Opinion, and in this Order--is determined to have been entered into in good faith, to be

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The Settlement Agreement means not only the initial settlement agreement filed on March 19, 1994, with its Exhibits, but also the supplemental agreements or addendums later filed with respect to Union Carbide Corporation, Union Carbide Chemicals and Plastics Company, Inc., INAMED; 3M; Applied Silicone; Wilshire Foam Products, Inc.; Wilshire Advanced Materials, Inc., and Wilshire Technologies, Inc.

non-collusive, to be reasonable, fair, and adequate, to be in the best interests of the class, and therefore is approved. Based on, subject to, and incorporating such provisions, it is hereby ORDERED and ADJUDGED as follows:

1. Heidi Lindsey and the other designated Representative Plaintiffs under Order No. 15 shall have and recover for themselves and other members of the plaintiffs' class:

(a) from Dow Corning Corporation the sum of $2,018,740,000.00;

(b) from Baxter Healthcare Corp. and Baxter International, Inc., the sum of $555,790,000.00;

(c) from Medical Engineering Corporation and Bristol-Myers Squibb Co. the sum of $1,154,290,000.00;

(d) from Minnesota Mining & Manufacturing Co. the sum of $325,000,000.00;

(e) from Applied Silicone Corporation the sum of $250,000.00;

(f) from Wilshire Technologies, Inc., the sum of $8,000,000.00;

(g) from Union Carbide Corporation the sum of $138,000,000.00; and

(h) from McGhan Medical Corp. the sum of $25,000,000.00.

2. The provisional certification of the class for settlement purposes, with certain modifications, is confirmed.

(a) Except as provided in (b), the class on whose behalf this judgment is entered consists of--

(1) all persons, wherever located, who have been implanted before June 1, 1993, with one or more breast implants (whether or not already or later removed), with respect to any claim against a Settling Defendant or Released Party for their own personal injury or death that may be asserted as due in whole or part to any breast implant;

(2) every child, wherever located, born before April 1, 1994, whose natural mother is a person described in subparagraph (1) above and who was born after the date his or her mother had a breast implant, with respect to any claim against a Settling Defendant or Released Party for his or her own personal injury or death that may be asserted as due in whole or part to his or her mother's having had a breast implant; and

(3) all persons or entities (including estates, representatives, spouses, children, relatives, and "significant others"), wherever located, with respect to any claim against a Settling Defendant or Released Party that they may assert independently or derivatively because of their personal relationship to a person described in subparagraph (1) or (2) above.

(b) Excluded from the class are the following:

(1) breast-implant recipients all of whose breast implants can be identified as manufactured or distributed by Porex Medical Technologies Corp., Koken Co., Ltd., or other foreign manufacturers not listed in Exhibit A or B to the Settlement Notice;

(2) breast-implant recipients who, as of April 1, 1994, were not citizens or permanent resident aliens of the United States if all of their breast implantations were performed outside the United States and--

(A) they have received any compensation for breast implant injuries or expenses from a Settling Defendant under the laws or procedures of another country; or

(B) they as of April 1, 1994, resided or were domiciled in Australia, or resided or had received a breast-implant in either the Province of Ontario or the Province of Quebec, Canada, except that such persons may, on an individual and purely 'opt-in' basis, become voluntary "Foreign Claimant' members of the settlement class. To opt in, such persons must file a Registration Form with the Claims Administrator, P.O. Box 56666, Houston, Texas, USA, 77256, post-marked no later than December 1, 1994. By voluntarily opting in through this registration, such persons--

(i) will be deemed to waive any objections and to accept the general terms of the settlement applicable to Foreign Claimants, and

(ii) will have all rights and benefits accorded to Foreign Claimants, including the right to opt out after the court determines the projected amounts payable to Foreign Claimants under the Disease Compensation Schedule. If an opting-in Foreign Claimant should later elect such opt-out right, the Settling Defendants will be precluded from asserting in a defense based on a statute of limitations, statute of repose, or similar proscription the period of time from January 24, 1992, to the date that is 30 days after such person elects to opt-out of the class.

(3) breast-implant recipients who, before June 17, 1994, shall have separately settled with a Settling Defendant, providing a general release of claims related to breast implants, unless (A) they were not represented by counsel in such settlement and the settlement involved a payment of less than $15,000 or (B) they demonstrate by clear and convincing evidence that their settlement was induced by a Settling Defendant's fraud;

(4) breast-implant recipients who, before June 17, 1994, shall have obtained and collected a judgment against a Settling Defendant on a breast-implant claim or, after a trial on the merits, shall have had a final judgment entered

against them on a breast-implant claim in favor of a Settling Defendant;

(5) breast-implant recipients who (during the "First Opt Out" period) elect to exclude themselves from the Settlement Class by return of a completed Exclusion Form, received or postmarked no later than June 17, 1994, or whose Exclusion Form, though received or postmarked after that date, is accepted by the Court as timely; and

(6) any person or entity described in paragraph 2(a)(3) whose status as a class member depends on class membership of a recipient excluded under paragraphs 2(b)(1) through 2(b)(5).

(c) As used in this Order and Judgment, the terms "Settling Defendants" and "Released Parties" mean those persons and entities listed or described in Schedules A and B to the Settlement Notice.

(d) A list of persons excluding themselves from the class will, in order to protect privacy interests to the extent possible, be maintained under seal by the court, with the identity of such persons subject to disclosure only to the extent necessary to protect the rights of the various parties (such as to determine whether a person is precluded from instituting or maintaining some other action).

3. Except as otherwise provided in the terms of settlement as approved by the court:

(a) the Settling Defendants and Released Parties are forever released from any and all claims which any member of the class had, has, or may have in the future against any of such persons and entities with respect to any existing or future claim, known or unknown, accrued or unaccrued, for personal injury or death that may be asserted as due in whole or part to any breast implant;

(b) each member of the class is barred and permanently enjoined from instituting, asserting, or prosecuting against any of the Settling Defendants or Released Parties in any pending or future action in any federal or state court in this country, or in any court or tribunal in any other country, any and all claims which such individual had, has, or may have in the future against any of such persons and entities with respect to any existing or future claim, known or unknown, accrued or unaccrued, for personal injury or death that may be asserted as due in whole or part to any breast implant;

(c) other persons and entities, not parties to the settlement agreement, against whom members of the class may assert claims for breast-implant related injuries or death are barred from making claims for contribution or indemnification against the Settling Defendants and Released Parties to the extent described in the accompanying Opinion, but are not precluded from asserting any rights to set-off, credit, or reduction that may be allowed under applicable state law; and

(d) other persons and entities, not parties to the settlement agreement, who may have claims for subrogation or reimbursement arising from payment or medical expenses or providing medical services to class members, are barred from making such claims against the Settling Defendants and Released Parties, but are not by this judgment precluded from subsequently attempting to institute or pursue such claims against the settlement fund or class members.

4. Costs are taxed against the settlement funds paid by the defendant.

5. Under Fed. R. Civ. P. 54(b), the court expressly determines that there is no just reason for delay and expressly directs that this judgment, upon filing in CV 94-P-11558-S, be deemed as a final judgment with respect to all claims by members of the class against the defendants herein with respect to breast-implant related injuries or death.

6. Without deferring or delaying the finality of this order and judgment, this court retains exclusive, general, and continuing jurisdiction as needed or appropriate in order to administer, supervise, implement, interpret, or enforce the settlement, including the investment, conservation, protection, allocation, and distribution of the settlement funds.

This the lst day of September, 1994.

/s/ Samuel C. Pointer, Jr.
Samuel C. Pointer, Jr.
United States District Judge

THE NUREMBERG CODE OF ETHICS IN MEDICAL RESEARCH

(1) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be so conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps in those experiments where the experimental physicians also serve as subjects.

(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he

has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.